BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0029; FRL-9352-5]

Cyflufenamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of cyflufenamid in or on multiple commodities which are identified and discussed later in this document. Nippon Soda Co., Ltd., c/o Nisso America, Inc requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION)**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2009-0029; FRL-9352-5, is available either electronically through

http://www.regulations.gov or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Samantha Hulkower, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603-0683; e-mail address: *hulkower.samantha@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not

listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0029 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any Confidential Business Information (CBI) for inclusion in the public docket. Information

not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0029, by one of the following methods:

● *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

● *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

● *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of April 8, 2009 (74 FR 15971)(FRL-8407-4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8F7488) by Nippon Soda Co., Ltd., c/o Nisso America, Inc, 45 Broadway, Suite 2120, New York, NY 100006. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide cyflufenamid, in or on cucurbit vegetables (crop group 9) at 0.05 parts per million (ppm); pome fruit (crop group 11), 0.05 ppm; apple, wet pomace, at 0.10 ppm;

small fruit vine climbing, except fuzzy kiwifruit (subgroup 13-07F) at 0.15 ppm; grape, raisin, at 0.30 ppm, and low growing berry (subgroup 13-07G), except cranberry, at 0.20 ppm. That notice referenced a summary of the petition prepared by Nippon Soda Co., Ltd., c/o Nisso America, Inc, the registrant, which is available in the docket, at *http://www.regulations.gov*. There were no comments received in response to the notice of filing

Based upon review of the data supporting the petition, EPA has slightly increased the tolerances for pome fruit (Crop Group 11), 0.05 ppm to 0.06 ppm, and cucurbits (Crop Group 9), 0.05 to 0.07 ppm. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for cyflufenamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with cyflufenamid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Cyflufenamid has low acute toxicity via the oral, dermal and inhalation routes of exposure. Though slightly irritating to the eye, cyflufenamid is not a skin irritant or sensitizer. In the mammalian toxicology database, the liver was the primary target organ for cyflufenamid toxicity. Across species, duration and gender, changes in weight, clinical chemistry and pathology indicated treatment-related perturbations in and adverse effects on liver function.

Thyroid effects due to treatment with cyflufenamid, seen only in the rat, included increased follicular cell hypertrophy (as well as increased organ weight) and neoplastic thyroid follicular adenomas. Kidney effects related to treatment included increased kidney weight accompanied by tubular vacuolation and slight decreases in sodium and chloride concentrations.

Treatment-related cardiotoxicity was noted in the rat and mouse feeding studies. Observed myocardial vacuolation and lipidosis may be attributed to decreased lipid metabolism; cyflufenamid caused an approximately 50% inhibition of carnitine palmitoyltransferase in both rat and mouse heart microsomal fractions in a non-guideline mechanistic study. Carnitine palmitoyltransferase is involved in the transport of long chain fatty acids into the mitochondrial matrix for oxidation. Fatty acid oxidation is an important source of energy for ATP production in the mitochondria.

Cyflufenamid-induced brain vacuolation was specific to the dog and not associated with any apparent clinical sign of neurotoxicity. Supplementary studies investigating this phenomenon determined that vacuolation was due to myelin edema affecting the white matter of the cerebrum and thalamus. Furthermore, this brain lesion was partially reversed after a 13-week recovery period (following 90-day exposure) and fully reversed after a 26-week recovery period. This effect was not observed in any other species. A subchronic neurotoxicity study in rats showed no evidence of neurotoxicity.

Effects on reproductive organs and/or parameters were noted in several subchronic studies at doses greater than the respective Lowest Observed Adverse Effect Level (LOAELs). Decreased uterus and cervix weights, adrenal cortical hypertrophy and reduced quality and quantity of spermatozoa were observed in dogs. Leydig cell hypertrophy was observed in rats and mice. It is unclear what toxicological significance should be ascribed to these findings since they may be secondary to systemic toxicity or hepatic enzyme induction. Mating performance and fertility in the P/F_0 generation were both unaffected by treatment with cyflufenamid in the 2-generation reproductive toxicity study in rats. Sex ratio, sexual maturation, estrous cyclicity, sperm quantity and quality,

mating performance and fertility, gestation and viability indices in the F_1 generation were all unaffected by treatment.

Cyflufenamid is classified as "likely to be carcinogenic to humans." This was based on the presence of two tumor types in two species: thyroid follicular cell tumors in male rats and liver tumors in male mice. There is no concern for mutagenicity or clastogenicity. The unit risk, Q_1^*, of cyflufenamid based upon male mouse liver combined adenoma and carcinoma tumor rates is 6.61×10^{-3} $(mg/kg/day)^{-1}$ in human equivalents.

Specific information on the studies received and the nature of the adverse effects caused by cyflufenamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Human Health Risk Assessment," docket ID number EPA-HQ-OPP-2009-0029.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a

population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for cyflufenamid used for human risk assessment is shown in Table 1 below. No hazards were identified for acute dietary across all populations. For dermal short and intermediate term exposures no adverse effects were observed in the dermal toxicity study and there are no concerns for developmental or neurological toxicities, therefore no hazards are expected for these exposure scenarios.

Table 1.—Summary of Toxicological Doses and Endpoints for Cyflufenamid for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Chronic dietary (All populations)	NOAEL= 4.4 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	cRfD = 0.044 mg/kg/day cPAD = 0.044 mg/kg/day	Combined Chronic Toxicity/ Carcinogenicity Study in Rats LOAEL = 22 mg/kg/day based on decreased body weight

			gain; increased thyroid/parathyroid weight, increased liver weight and centrilobular hepatocytic hypertrophy
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL= 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Prenatal Developmental Study in Rabbits Maternal LOAEL = 10 mg/kg/day based on decreased body weight, body weight gain and food consumption
Inhalation short-term (1 to 30 days) and intermediate-term (1 to 6 months)	NOAEL= 5 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	Prenatal Developmental Study in Rabbits Maternal LOAEL = 10 mg/kg/day based on decreased body weight, body weight gain and food consumption
Cancer (Oral, dermal, inhalation)	Likely to be carcinogenic to humans. Quantification of cancer risk was recommended. The Q_1* value is 6.61 x 10^{-3} $(mg/kg/day)^{-1}$.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal

to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to cyflufenamid, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from cyflufenamid in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for cyflufenamid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Continuing Survey of Food Intake by Individuals (CSFII). As to residue levels in food, this dietary assessment was based on average field trial residues for all proposed crops and 100% crop treated (CT). Empirical processing factors were used for apple juice and grape juice. A separate tolerance was set for grape, raisin; therefore, the processing factor for this commodity was set at 1. For all other processed commodities, Dietary Exposure Evaluation Model (DEEM) version 7.81 default processing factors were assumed.

iii. *Cancer*. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., *chronic exposure*.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use PCT information in the dietary assessment for cyflufenamid. One-hundred PCT were assumed for all food commodities.

Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for cyflufenamid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of cyflufenamid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of cyflufenamid for acute exposures are estimated to be 1.14 parts per billion (ppb) for surface water and 4.68 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 0.03

ppb for surface water and 4.68 ppb for ground water. Chronic exposures for cancer assessments are estimated to be 0.01 ppb for surface water and 4.68 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, no toxic effects attributable to a single exposure to cyflufenamid have been identified; therefore, an acute reference dose (aRfD) has not been established and an acute dietary exposure assessment was not conducted.

For chronic and cancer dietary risk assessments, the ground water concentration value of 4.68 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Cyflufenamid is proposed to be registered for the following uses that could result in residential exposures: Mixing, loading, and applying a soluble concentrate formulation of cyflufenamid for treatment of ornamental plantings and trees. EPA assessed residential exposure using the following assumptions: Based on the use patterns, residential handlers could be exposed to cyflufenamid on a short-term basis. A short-term dermal endpoint was not identified; therefore, only short-term non-cancer inhalation risks and cancer risks for residential handlers were assessed.

When determining the potential for residential post-application exposure, the Agency considers foliar residues, leaf to skin/hand residue transfer, children's hand-to-

mouth residue transfer, and exposure time. In the case of cyflufenamid, potential exposure to adults and children would be negligible for the following reasons:

● Activities such as pruning/thinning ornamentals or playing in and around ornamentals when residues may be present on the day of the application are unlikely to co-occur;

● If present, leaf to skin residue transfer would be negligible because of the minimal frequency and duration of contact;

● Children young enough to exhibit hand-to-mouth behavior would not typically play in ornamental beds or trees.

Based on the frequency of application and unlikely potential for post-application exposure, residential post-application risks were not quantitatively assessed; thus, there are no postapplication residential risk concerns for this use pattern.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA has not found cyflufenamid to share a common mechanism of toxicity with any other substances, and cyflufenamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cyflufenamid does not have a common

mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is no evidence of susceptibility following *in utero* and/or postnatal exposure in the developmental toxicity studies in rats or rabbits, and in the 2-generation rat reproduction study. There are no residual uncertainties concerning pre- and postnatal toxicity and no neurotoxicity concerns.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cyflufenamid is complete, with the exception of an acute neurotoxicity study (ACN, OPPTS 870.6200a), The absence of the this study does not raise any uncertainties with regard to the safety of infants and children for the

following reasons. First, no acute affects have been attributed to cyflufenamid. In an acute oral toxicity study, adverse effects were noted on the day of administration (limit dose) but not thereafter; clinical signs of piloerection, hunched posture, unsteady gait, pallid extremities, increased salivation, ungroomed appearance and abnormal respiration were observed in the majority of animals receiving 5,000 mg/kg and generally resolved by Day 2 of the study. Second, an acceptable, guideline subchronic neurotoxicity study is available and in it repeat exposure to doses up to approximately 500 mg/kg/day did not elicit any neurotoxic effects as assessed in the functional observational battery, motor activity, neurohistopathology or brain morphometrics. Third, cyflufenamid is not an apparently neurotoxic chemical based on clinical toxicity assessments incorporated within the developmental and chronic rat studies. In several short-term studies in rats (subacute and subchronic feeding, plaque-forming cell assay, one-generation pilot, developmental toxicity), no neurobehavioral signs were observed at the highest doses tested. While the relevant and reversible effect of brain vacuolation was observed in the subchronic dog study at approximately 70 mg/kg/day, it is observed in the absence of overt neurotoxicity and nowhere else in the toxicology database. Finally, based on this information, an acute neurotoxicity screening test is very unlikely to yield a point of departure less than the chronic NOAEL of 4.4 mg/kg/day if any adverse effects are observed at all. Even if the chronic point of departure was used in assessing acute risk, there would be no risk concern based on acute dietary exposure.

ii. There is no indication that cyflufenamid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that cyflufenamid results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary assessment assumed 100% crop treated for all commodities and utilized average field trial residues for all proposed crops, default and empirical processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to cyflufenamid in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by cyflufenamid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, cyflufenamid is not expected to pose an acute risk.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to cyflufenamid from food and water will utilize 1 % of the cPAD for all infants (<1 year old) the population group receiving the greatest exposure.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level. Because no short-term adverse effect was identified, cyflufenamid is not expected to pose a short-term risk.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, cyflufenamid is not expected to pose a intermediate-term risk.

5. *Aggregate cancer risk for U.S. population*. Aggregate cancer exposure takes into account residential handler exposure, plus chronic exposure to food and water (considered to be a background exposure level). The aggregate cancer risk (food, water, and residential) is 9.7×10^{-7}.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cyflufenamid residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate multiresidue methods test data for cyflufenamid were submitted. Acceptable recoveries of cyflufenamid from a non-fatty matrix (grape) were achieved

under Protocol E. Acceptable recoveries from a fatty matrix (milk) were also achieved under Protocol F. EPA recommends that Food and Drug Administration (FDA) multiresidue methods be used as the primary enforcement method. The submitted data will be forwarded to the FDA for further evaluation.

Adequate enforcement methodologies are available to enforce the tolerance expression. The LC/MS/MS method (Method 070276) was submitted for the determination of cyflufenamid residues in/on pome fruit, cucurbit vegetables, grapes, and strawberries. The proposed enforcement method (Method 070276) which monitors only one transition ion, in combination with the FDA multiresidue method meets the OPPTS Residue Chemistry Test Guidelines for acceptable tolerance enforcement methods (SOP Number ACB-019). An enforcement method for livestock commodities is not needed because tolerances for cyflufenamid residues of concern in meat, milk, poultry, and eggs are not required to support the proposed uses based on the results of the goat metabolism study and the calculated dietary burden.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and

Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for cyflufenamid. Cyflufenamid is not registered in Canada.

C. Revisions to Petitioned-For Tolerances

The EPA increased the proposed tolerance for pome fruit crop group 11 from 0.05 ppm to 0.06 ppm and for cucurbit crop group 9 from 0.05 ppm to 0.07 ppm. These changes were made by EPA based on North American Free Trade Agreement (NAFTA) tolerance calculation procedures according to the Standard Operating Procedure (SOP) *Guidance for Setting Pesticide Tolerances Based on Field Trial Data.*

V. Conclusion

Therefore, tolerances are established for residues of cyflufenamid, in or on Apple, wet pomace, 0.10 ppm; Berry, low growing, subgroup 13-07G, except cranberry, 0.20 ppm; Fruit, pome, group 11, 0.06 ppm; Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F, 0.15 ppm; Grape, raisin, 0.30 ppm; Vegetable, cucurbit, group 9, 0.07 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final

rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal

Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 15, 2012.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.667 is added to subpart C to read as follows:

§ 180.667 Cyflufenamid, tolerance for residues.

(a) *General.* Tolerances are established for residues of the fungicide cyflufenamid, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only cyflufenamid, [*N(Z)]-N*-[[(cyclopropylmethoxy)amino][2,3-difluoro-6-(trifluoromethyl)phenyl]methylene]benzeneacetamide.

Commodity	Parts per million
Apple, wet pomace	0.10
Berry, low growing, subgroup 13-07G, except cranberry	0.20
Fruit, pome, group 11	0.06
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	0.15
Grape, raisin	0.30
Vegetable, cucurbit, group 9	0.07

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012-15595 Filed 06/26/2012 at 8:45 am; Publication Date: 06/27/2012]